

REMARKS

Restriction

Restriction to one of the following inventions has been required under 35 USC 121:

- I. Claims 1-14 and 21-31, drawn to a diagnostic method for quantifying a subject suffering from a symptom caused by traumatic brain injury and a method for confirming the occurrence of a traumatic brain injury event, classified in class 435, subclass 7.1.
- II. Claims 15-20, drawn to a diagnostic kit, classified in class 435, subclass 975.
- III. Claims 32-37, drawn to a diagnostic kit, classified in class 435, subclass 810.

The Examiner has also required a species election for the invention of Group I;

species

- A. S-100 $\beta$  (claims 1-4, 9-14 and 21-31)
- B. neuron specific enolase (claims 1-3, 5, 9-14 and 21-31)
- C. myelin basic protein (claims 1-3, 6, 9-14 and 21-31)
- D. glial (claims 1, 2, 7 and 9-14)
- E. neuronal (claims 1, 2, 7, and 9-14)
- F. axonal (claims 1, 2, 7 and 9-14)

Election

Applicants herein elect, without traverse, Group III (original claims 32-37 and new claim 38, drawn to a diagnostic kit) for prosecution on the merits. An election of species is not applicable to Applicants' election of Group III, since the Examiner has required an election of species with an election of Group I only.

Claim Status/Support for Claim Amendments

Claims 1, 2, 8-15, 21-27 and 31-37 have been amended. Claims 3-7, 16-20 and 28-30 have been cancelled. Claim 38 has been added. Claims 1, 2, 8-15, 21-27 and 31-38 remain pending in the instant application.

In view of the Examiner's restriction requirement, Applicants retain the right to present claims 1, 2, 8-15, 21-27 and 31 in a divisional application.

No new matter has been added by the amendments to the claims. Claims 1, 15 and 21 have been amended to indicate that a combination of markers can be analyzed using the claimed diagnostic methods and kits (page 18, lines 6-8 of the instant specification). The markers (S-100 $\beta$ , NSE, MBP, glial markers, neuronal markers and axonal markers) from which combinations can be selected were disclosed in claims 3-7 as originally filed. Claims 1, 15, 21 and 32 have been amended to clarify that the analyzing step involves

measuring and comparing concentrations of markers in a sample. This is supported in numerous parts of the instant specification, for example, at page 1, lines 7-10; page 18, line 24 to page 19, line 2 and page 21, lines 3-21. Dependent claims have been amended to properly depend from the independent claims as amended. The claims have also been amended to correct minor grammatical and formatting errors and to clarify abbreviations used.

No new matter has been added by the addition of claim 38. Claim 38 indicates that the fourth marker protein as recited in claim 36 can be selected from glial markers, neuronal markers and axonal markers (page 25, lines 12-16 of the instant specification).

CONCLUSION

Now that Applicants have fully responded to the Office Action mailed on October 20, 2003, an examination on the merits is respectfully requested.

Respectfully submitted,

*Ferris H. Lander*

Ferris H. Lander  
Registration # 43,377

McHale & Slavin, P.A.  
2855 PGA Boulevard  
Palm Beach Gardens, FL 33410  
(561) 625-6575 (Voice)  
(561) 625-6572 (Fax)  
\Ns2\client files\2100-2199\2132 -Syn-X\2132\_000022 - Meth.forDiag. and Dist.  
Traumatic\Amendments\2132\_022\_RR.wpd